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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,664	01/22/2004	David J. Beebe	282.033	5152
7590	05/15/2006			
			EXAMINER	
			GILBERT, ANDREW M	
			ART UNIT	PAPER NUMBER
			3767	
DATE MAILED: 05/15/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/762,664 Examiner Andrew M. Gilbert	BEEBE ET AL. Art Unit 3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 April 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
  - 4a) Of the above claim(s) 9, 17, 20 and 25 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 10-16 and 18-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 22 January 2004 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/10/2004</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

***Election/Restrictions***

1. Claims 9, 17, 20, and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/27/2006.
2. Applicant's election with traverse of Species I: Figs 1-4 with claims 1-8, 10-16, 18, 19, 21-24 readable thereon in the reply filed on 4/27/2006 is acknowledged. The traversal is on the ground(s) that the species are not independent and distinct and that there is no serious burden on the Examiner. This is not found persuasive because the Species are independent and distinct. The non-elected species have elements including a second reservoir that can be manually depressed by a user and having a docking station providing support for the pump and needle cannula. These elements may be considered a point of novelty, are not obvious variants of the elected species, and require separate subclass searches than required for the elected species. Thus, the Examiner holds that the species are independent and distinct and that there is a burden on the Examiner. The Examiner does agree that claims 1-2, 10-12, 18-19 are generic to all embodiments of the present application.

The requirement is still deemed proper and is therefore made FINAL.

***Drawings***

3. The drawings are objected to because the lines are not clear and legible; the reference numbers are not legible; and black shading is not permitted. Corrected

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drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

4. The disclosure is objected to because of the following informalities:
  - a. The "Cross Reference to Related Applications" paragraph on pg 1, Ins 5-8 needs to be updated to reflect the abandonment of application 10/640345.
  - b. On pg 10, In 28, the Examiner believes that the "pressure source cavity 72" should reference "70" instead of "72" (see Figs and pg 10, Ins 22-23). Appropriate correction is required.

***Claim Objections***

5. Claims 5, 14, and 22 recite the limitation "the trigger receiving portion" in ln 4 respectively. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6, 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by van Lintel, hereafter "Lintel" (5224843). Lintel discloses a microfluidic device (Fig 1) for delivering a drug to an individual comprising: a reservoir (15); an output needle (10; col 3, Ins 37-38) having an input in communication with the reservoir and an output receivable within the individual; and a pressure source (13) engageable with the reservoir; further comprising a flexible membrane (12) isolating the pressure source from the reservoir; further comprising a valve (18) operatively connecting the input of the output needle and the reservoir (Fig 1-2; wherein the valve defines a chamber (18d) having an input (col 4, Ins 38-40) communicating with the reservoir and an output (col 4, Ins 38-43) communicating with the input of the output needle; wherein the valve includes a flexible membrane (18a) and a trigger (18c) disposed in the trigger receiving portion (Fig 1) in the chamber of the valve and having a first configuration (col 4, Ins 26-50) preventing the flow of the drug through the chamber and a second configuration (col 4, Ins 26-50) allowing the flow of the drug through the chamber; further comprising a

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first sensing needle (10; col 3, Ins 37-38) having an input receivable in the individual and an output (3) within the trigger receiving portion of the chamber (Fig 1), the first sensing needle being capable of allowing physiological fluids to pass from the individual to the trigger receiving portion of the chamber; wherein the output needle is removable from the body (10; col 3, Ins 37-38).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lintel. Lintel discloses the invention substantially as claimed except for expressly disclosing a second sensing needle having an input receivable in the individual and an output within the trigger receiving portion of the chamber, the second sensing needle allowing physiological fluids to pass from the individual to the trigger receiving portion of the chamber. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a second sensing needle having an input receivable in the individual and an output within the trigger receiving portion of the chamber, the second sensing needle allowing physiological fluids to pass from the individual to the trigger receiving portion of the chamber because the Applicant has not disclosed that having a second sensing needle provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill

in the art would have expected the Applicants invention to perform equally well with the single sensing needle of Lintel because it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Therefore, it would have been an obvious matter of design choice to modify Lintel to obtain the invention as specified in claim 7.

10. Claims 18, 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lintel in view of Connelly et al (6689100). Lintel discloses the invention substantially as claimed except for an adhesive for affixing the body to the individual. Connelley et al teaches that it is known to have an adhesive (38) for affixing the body to the individual for the purpose of preventing leakage and ensuring efficiency of the delivery (col 4, Ins 34-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Lintel with the adhesive as taught by Connelly et al for the purpose of preventing leakage and ensuring efficiency of the delivery (col 4, Ins 34-36).

11. Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lintel in view of Beebe et al (6523559). Lintel discloses the invention substantially as claimed except for wherein the trigger includes a hydrogel post, the hydrogel post expandable in response to exposure to a predetermined condition. Beebe et al teaches that it is known to have wherein the trigger includes a hydrogel post (56), the hydrogel post expandable in response to exposure to a predetermined condition (col 5, Ins 29-67) for the purpose of having a self-regulating microfluidic device responsive to changes in value of a solution to regulate the feedback to compensate and return the value of the

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solution to the desired level without the need for any external power sources and/or electronics. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the trigger as taught by Lintel with the hydrogel post as taught by Beebe et al for the purpose of having a self-regulating microfluidic device responsive to changes in value of a solution to regulate the feedback to compensate and return the value of the solution to the desired level without the need for any external power sources and/or electronics.

12. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lintel in view of Beebe et al in further view of Connelly et al. Lintel and Beebe et al disclose the invention substantially as claimed except for an adhesive for affixing the body to the individual. Connelly et al teaches that it is known to have an adhesive (38) for affixing the body to the individual for the purpose of preventing leakage and ensuring efficiency of the delivery (col 4, lns 34-36). See above discussion in regard to claims 8 and 16.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew Gilbert

KEVIN SIRMONS  
PRIMARY EXAMINER

